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Local Attorney for Linda P. Smith

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH  
CENTRAL DIVISION

LINDA P. SMITH,

*Plaintiff*

v.

XAVIER BECERRA, in his capacity  
as the Secretary of the United States  
Department of Health and Human  
Services,

*Defendant*

Case No. 1:21-cv-00047-CMR

JOINT PROPOSED SCHEDULING  
ORDER

JURY TRIAL DEMANDED

Magistrate Judge Romero

Pursuant to Local Rule 7-4(a)(5), the parties file this joint proposed scheduling order.

**Plaintiff's Statement:**

This case appears to be a situation not contemplated by the Local Rules. First, while this is a case seeking, *inter alia*, Medicare reimbursement from the Secretary of HHS, the case is brought pursuant to the Social Security Act (42 U.S.C. § 405(g)). The Social Security Act has explicit provisions requiring the filing of the certified administrative record with the Secretary's Answer (*i.e.*, 60 days after service). While the Local Rules have carve outs for Social Security cases, the Local Rules do not address Medicare cases which arise under the same statute. Thus, the Secretary is already in violation of 42 U.S.C. 405(g), because the Secretary has already responded to the Complaint but has failed to file/produce the administrative record.<sup>1</sup>

Second, while some of the issues may be resolved using the “substantial evidence” or “arbitrary and capricious” standards, other issues/theories may not. For example, the Complaint seeks a determination that CMS 1682-R issued in violation of law and for the Court to set it aside. That is based on the Secretary's failure to comply with the Medicare specific notice and comment provisions (*see* 42 U.S.C. § 1395hh).

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<sup>1</sup> Though the Secretary's representative avers that the record will be served by June 25, 2021.

Accordingly, Plaintiff believes an Answer complying with FED.R.CIV.P. 8 which either admits or denies each of the allegations of the Complaint is needed so that Plaintiff has notice of what is or is not disputed for the coming motion practice. Plaintiff understands that the Secretary opposes complying with the Federal Rules of Civil Procedure with regard to an Answer. Respectfully, Plaintiff believes that that position is contrary to the Supreme Court's direction in *Iqbal/Twombly*. For the same reasons, Plaintiff believes that traditional motion practice with regard to motions for summary judgment should be applied in this case.

Plaintiff believes that the Secretary's denial of her claim for CGM coverage to treat her diabetes fails to comply with the law because it is based on CMS 1682-R (attempting define Mrs. Smith's CGM as not "primarily and customarily used to serve a medical purpose", which issued illegally. In addition, Mr. Smith contends that the decision is not supported by substantial evidence/is arbitrary and capricious because the idea that a CGM is not "primarily and customarily used to serve a medical purpose" is, *inter alia*, frivolous as one court has already found. Further, Mrs. Smith asserts that the Secretary is estopped from denying coverage for her in light of prior, final approvals by the Secretary for Mrs. Smith's CGM.

Further, because of the involved and somewhat new issues of compliance with the notice and comment portion of the Medicare Act and collateral estoppel, Plaintiff requests leave to file two summary judgment briefs: one directed toward all issues

other than collateral estoppel and another directed toward collateral estoppel. Plaintiff believes that the Court would benefit from oral argument on the motions and requests the same.

Given the Secretary's failure to fully concede coverage, Mrs. Smith's contention that denial on any basis is barred by collateral estoppel, and Mrs. Smith's demand that CMS 1682-R be declared illegally issued, no judgment according Mrs. Smith the relief sought in the Complaint could be entered. If the Secretary is prepared to stipulate to a judgment finding coverage and also stipulating that CMS 1682-R issued illegally and is unenforceable, then a judgment in Mrs. Smith's favor could be granted. Absent that, this case must proceed.

Date	Action
June 25, 2021	Secretary files/serves administrative record (though 42 U.S.C. ¶ 405(g) required this by June 7, 2021).
June 28, 2021	Secretary serves an Answer compliant with FED.R.CIV.P. 8. Objections, if any, to the record due.
July 2, 2021	Any pre-merits motions due.
July 6, 2021	Plaintiff and the Secretary file motions for summary judgment addressing all causes of action.
August 3, 2021	Oppositions due.
August 17, 2021	Replies due.

**Defendant's Statement:**

As the Secretary has explained, *see* ECF No. 10, the complaint challenges a decision by the Medicare Appeals Council, Docket No. M-19-1973, denying coverage under Medicare Part B for three claims. The first claim is for a MiniMed 630G system. This device is a durable insulin pump, which is covered as durable medical equipment (DME) under the Medicare statute and regulations. The Medicare Appeals Council erred in denying coverage for this item.

The second and third claims are for disposable sensors used with the insulin pump, which also functions as a continuous glucose monitor (CGM). Coverage for the disposable sensors was denied, because the continuous glucose monitor function of the durable device does not satisfy CMS Ruling 1682-R, which interprets the Medicare statute and regulations as applied to continuous glucose monitors. This denial was also erroneous, because it failed to consider an important aspect of the problem: whether the sensors were reasonable and necessary for the operation of the insulin pump function of the device, which uses sensor data to determine when to automatically shut off the flow of insulin.

Because the challenged decision was erroneous, this Court should enter judgment in favor of Plaintiff and remand to the Secretary for payment of the claim for the insulin pump, and determination of whether the sensors should be covered as reasonable and necessary for the operation of the insulin pump. A remand on these

terms would also allow the Secretary to reconsider his determination that the continuous glucose monitor function of this insulin pump does not entitle Plaintiff to coverage of the sensors in question. The Secretary recently published a notice of proposed rulemaking which would, if finalized, “classify CGM systems” like the device at issue here “as DME” covered by Medicare Part B, as Plaintiff argues that they are. 85 Fed. Reg. 70,358, 70,403–04 (Nov. 4, 2020).

If the Court does not enter judgment against the Secretary on the terms suggested above, it will need to set a schedule for briefing on the merits of Plaintiff’s claims. The parties agree that the administrative record should be served and filed on or before June 25, 2021; that objections to the administrative record should be due on or before June 28, 2021; and that any other pre-merits motions should be due by July 2, 2021.

The Secretary respectfully suggests that this case should be litigated under Local Civil Rule 7-4, and proposes that the remaining deadlines in this case be set from the time at which the Court chooses to enter a briefing schedule, as follows:

- Plaintiff to file her opening brief, in conformance with Local Civil Rule 7-4(a)(5)(D), no more than three weeks after this Court enters a scheduling order;

- The Secretary to file his answer brief, in conformance with Local Civil Rule 7-4(a)(5)(E), no more than three weeks after Plaintiff files her opening brief; and
- Plaintiff to file her reply brief, in conformance with Local Civil Rule 7-4(a)(5)(F), no more than two weeks after the Secretary files his answer brief.

Plaintiff does not offer any persuasive reason for this Court to depart from the Local Rule governing cases such as this one. Plaintiff implausibly suggests that the Rule does not apply whenever a complaint alleging an arbitrary and capricious agency action also includes an allegation of procedural error or statutory violation. If such common cases are outside of Local Civil Rule 7-4, then its streamlined procedures will be very easily avoided. And in place of the Local Rule, Plaintiff offers a wasteful and duplicative schedule in which the Secretary would file an unnecessary answer, and then the parties would file *three* simultaneous motions for summary judgment, *see supra* at 2 (“Plaintiff requests leave to file two summary judgment briefs”), followed by three oppositions and three replies, for a total of *nine briefs* where the Local Rule would call for only three.

The Secretary respectfully suggests that no departure from the Local Rule is warranted here. If, however, the Court decides to order the filing of an answer in

this case, the Secretary respectfully requests a deadline for the filing of that answer that is two weeks after the entry of the Court's order.

Dated: June 21, 2021

Respectfully submitted,

PARRISH LAW OFFICES

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